Office of Facilities, Acquisitions and Central Services[22]

Policy Evaluation and Support Staff.
Division of Contracts and Procurement Management.
Division of Construction and Facilities Support Contracting.
Division of Central Services.
Division of Real Property Management.
Project Analysis and Evaluation Staff.
Division of Facilities Planning, Engineering and Safety.
Facilities Planning Staff.
FDA Safety Staff.

OFFICE OF POLICY

Regulations Policy and Management Staff.
Policy Development and Coordination Staff.
Policy Research Staff.
International Policy Staff.

[63 FR 18314, Apr. 15, 1998]

§ 5.205 Chief Counsel, Food and Drug Administration.

The Chief Counsel to the Commissioner of Food and Drugs is the Associate General Counsel, Food and Drug Division, Office of the General Counsel, Department of Health and Human Services, Room 6–57, 5600 Fishers Lane, Rockville, MD 20857.

[46 FR 8455, Jan. 27, 1981, as amended at 56 FR 8709, Mar. 1, 1991. Redesignated at 62 FR 13824, Mar. 24, 1997]

§ 5.210 FDA Public Information Offices.

(a) *Dockets Management Branch (HFA–305).* The Dockets Management Branch Public Room is located in rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857. Telephone: 301–443–1753.

(b) *Freedom of Information Staff (HFI–35).* The Freedom of Information Public Room is located in rm. 12A–30, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6500

(c) *Press Relations Staff (HFI–40).* The Press Offices are located in rm. 15A–07, Parklawn Bldg., 5600 Fishers Lane, Rockville, MD 20857. Telephone: 301–827–6242; and in rm. 3807, FB–8, 200 C St. SW., Washington, DC 20204. Telephone 202–245–1141.

[63 FR 18317, Apr. 15, 1998]

[22] Mailing address: 12420 Parklawn Dr., Rockville, MD 20857

§ 5.215 Field structure.

NORTHEAST REGION

Regional Field Office: 850 Third Ave., Brooklyn, NY 11232.
Northeast Regional Laboratory: 850 Third Ave., Brooklyn , NY 11232–1593.
New York District Office: 850 Third Ave., Brooklyn, NY 11232–1593.
New England District Office: One Montvale Ave., Stoneham, MA 02180.
Buffalo District Office: Olympic Towers, 300 Pearl St., Buffalo, NY 14202.

CENTRAL REGION

Regional Field Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.
Baltimore District Office: 900 Madison Ave., Baltimore, MD 21201–2199.
Cincinnati District Office: 1141 Central Pkwy., Cincinnati, OH 45202–1097.
New Jersey District Office: Waterview Corporate Center, 10 Waterview Blvd., 3d Floor, Parsippany, NJ 07054.
Philadelphia District Office: U.S. Customhouse, Second and Chestnut Sts., rm. 900, Philadelphia, PA 19106.
Chicago District Office: 300 South Riverside Plaza, suite 550, South Chicago, IL 60606.
Detroit District Office: 1560 East Jefferson Ave., Detroit, MI 48207–3179.
Minneapolis District Office: 240 Hennepin Ave., Minneapolis, MN 55401–1912.

SOUTHEAST REGION

Regional Field Office: 60 Eighth St. NE., Atlanta, GA 30309.
Southeast Regional Laboratory: 60 Eighth St. NE., Atlanta, GA 30309.
Atlanta District Office: 60 Eighth St. NE., Atlanta, GA 30309.
Nashville District Office: 297 Plus Park Blvd., Nashville, TN 37217.
New Orleans District Office: 4298 Elysian Fields Ave., New Orleans, LA 70122.
Florida District Office: 555 Winderley Pl., suite 200., Maitland, FL 32751.
San Juan District Office: 466 Fernandez Juncos Ave., San Juan, PR 00901–3223.

SOUTHWEST REGION

Regional Field Office: 7920 Elmbrook Rd., Dallas, TX 75247–4982.
Dallas District Office: 3310 Live Oak St., Dallas, TX 75204.
Denver District Office: Bldg. 20, Denver Federal Center, Sixth and Kipling Sts., P.O. Box 25087, Denver, CO 80225–0087.
Kansas City District Office: 11630 West 80th St., Lenexa, KS 66214.
St. Louis Branch: 12 Sunnen Dr., St. Louis, MO 63143.

PACIFIC REGION

Regional Field Office: 1301 Clay St., suite 1180–N, Oakland, CA 94612–5217.
San Francisco District Office: 1431 Harbor Bay Pkwy., Alameda, CA 94502–7070.
Los Angeles District Office: 19900 MacArthur Blvd., suite 300, Irvine, CA 92612–2445.
Seattle District Office: 22201 23d Dr. SE., Bothell, WA 98021–4421.

[63 FR 18317, Apr. 15, 1998]

PART 7—ENFORCEMENT POLICY

Subpart A—General Provisions

Subpart B [Reserved]

Subpart C—Recalls (Including Product Corrections)—Guidelines on Policy, Procedures, and Industry Responsibilities

Subpart D [Reserved]

Subpart E—Criminal Violations

AUTHORITY: 21 U.S.C. 321–393; 42 U.S.C. 241, 262, 263b–263n, 264.

SOURCE: 42 FR 15567, Mar. 22, 1977, unless otherwise noted.

Subpart A—General Provisions

§7.1 Scope.

This part governs the practices and procedures applicable to regulatory enforcement actions initiated by the Food and Drug Administration pursuant to the Federal Food, Drug and Cosmetic Act (21 U.S.C. 301 *et seq.*) and other laws that it administers. This part also provides guidelines for manufacturers and distributors to follow with respect to their voluntary removal or correction of marketed violative products. This part is promulgated to clarify and explain the regulatory practices and procedures of the Food and Drug Administration, enhance public understanding, improve consumer protection, and assure uniform and consistent application of practices and procedures throughout the agency.

[43 FR 26218, June 16, 1978]

§7.3 Definitions.

(a) *Agency* means the Food and Drug Administration.

(b) *Citation* or *cite* means a document and any attachments thereto that provide notice to a person against whom criminal prosecution is contemplated of the opportunity to present views to the agency regarding an alleged violation.

(c) *Respondent* means a person named in a notice who presents views concerning an alleged violation either in person, by designated representative, or in writing.

(d) *Responsible individual* includes those in positions of power or authority to detect, prevent, or correct violations of the Federal Food, Drug, and Cosmetic Act.

(e) [Reserved]

(f) *Product* means an article subject to the jurisdiction of the Food and Drug Administration, including any food, drug, and device intended for human or animal use, any cosmetic and biologic intended for human use, and any item subject to a quarantine regulation under part 1240 of this chapter. *Product* does not include an electronic product that emits radiation and is subject to parts 1003 and 1004 of this chapter.

(g) *Recall* means a firm's removal or correction of a marketed product that the Food and Drug Administration considers to be in violation of the laws it administers and against which the agency would initiate legal action, e.g., seizure. *Recall* does not include a market withdrawal or a stock recovery.